K071858

Attachment 4

9.0 SUMMARY OF SAFETY AND EFFECTIVENESS

DENTAL MATRIX BAND

AUG 3 1 2007

Manufacturer:	Fly Cast Technologies, Inc. 30647 Countryside Drive Libertyville, Illinois 60048
Regulatory Affairs Contact:	Michele Vovolka P.O. Box 848 Grayslake, Illinois 60030
Telephone:	(847) 856-0355
Date Summary Prepared:	August 25, 2007
Product Trade Name:	Dental Matrix Band
Common Name:	Dental Matrix Band
Classification:	Class I
Predicate Devices:	
Description:	The Dental Matrix Band is made of medical grade stainless steel with a tin coating. The dental matrix bands are offered non-sterile single use.
Intended Use:	A dental matrix band is a non-sterile single use disposable device intended to be place around a tooth to keep filling material from bonding onto the other tooth. Matrix bands are used to form missing walls of prepared teeth. They shape and confine restorative materials to areas prepared to receive restorations.

Substantial Equivalence: The Dental Matrix Band is substantially equivalent to the Dentsply, Inc., Dental Matrix Band in that they provide the following characteristics:

- Intended use
- Size and configuration
- Base material

Summary of Testing: Materials were tested per ISO 10993 Biological Evaluation for Medical Devices for a surface indicating, skin, limited exposure device

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Fly Cast Technologies, Incorporated
C/O Ms. Michele H. Vovolka
Regulatory Consultant
Vantage Consulting International, Limited
PO Box 848
Grayslake, Illinois 60030

AUG 3 1 2007

Re: K071858
Trade/Device Name: Dental Matrix Band
Regulation Number: 21 CFR 872.4565
Regulation Name: Dental Hand Instrument
Regulatory Class: I
Product Code: DZN
Dated: June 21, 2007
Received: July 5, 2007

Dear Ms. Vovolka:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K071858

Attachment 3

510(k) Number (if known): _____

Device Name: Dental Matrix Band

Indications For Use:

A dental matrix band is a non-sterile single use disposable device intended to be place around a tooth to keep filling material from bonding onto the other tooth. Matrix bands are used to form missing walls of prepared teeth. They shape and confine restorative materials to areas prepared to receive restorations.

Prescription Use X AND/OR Over -The-Counter Use_____
(Part 21 CFR 801 Subpart D) (Part 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, ~~Office~~ of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K071858